

REMARKS

Applicant notes the Office's request for corrected drawings and states that the corrected drawings labeled Fig. 2, 3, 4, 5, 7, 8, 9, 13, 14, 15, and 16, and corresponding to the "Brief Description of the Drawings" section were submitted with the "Petition to Accept Color Photographs" filed on October 10, 2001.

Claims 1-6 and 8 are currently pending. Claim 7 has been cancelled. Claims 1, 5, and 6 have been amended. Support for amended claims 1, 5, and 6 can be found in the specification at, for example, the Brief Description of the Drawings and Example 2, at page 23, lines 12-14. As such, Applicant submits that no new matter has been added by way of this amendment.

In the final Office Action of May 13, 2003, the Office set forth the following rejections:

- 1) claim 6 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite;
- 2) claims 1 and 2 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Moutsatsos et al. (WO 99/11664);
- 3) claims 1, 2 and 4-7 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Riew et al. (Calcif. Tissue Int. 63:357-360 1998) as evidenced by Caplan et al. (U.S. 5,855,619);
- 4) claims 1, 2 and 4-7 were rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Cheng et al. (Calcif. Tissue Int. 68:87-94, 2001) as evidenced by Caplan et al.;
- 5) claims 1 and 3-8 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Moutsatsos et al. in view of Riew et al. or Cheng et al.;

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6) claims 1, 3, 5 and 8 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Riew et al. or Cheng et al.

These rejections are respectfully traversed for the reasons set forth below.

Reconsideration is respectfully requested.

I. Rejections under 35 U.S.C. § 112, second paragraph

The Office rejected claim 6 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for the recitation of “the BMP-2 gene” in line 1 of the claim. This rejection is respectfully traversed.

Applicant has amended claim 6 such that it no longer recites “the BMP-2 gene.”

As such, Applicant respectfully requests the withdrawal of this rejection.

II. Rejections under 35 U.S.C. § 102(b)

The Office rejects claims 1-2 under 35 U.S.C. § 102(b) as allegedly anticipated by Moutsatsos et al. (WO 99/11664). This rejection is respectfully traversed for the reasons set forth below.

Claim 1, as amended, is directed to a pharmaceutical composition for application at a site requiring new bone, cartilage or connective tissue formation in a subject, comprising a plurality of bone marrow stromal cells (MSCs) isolated from the subject, wherein the MSCs comprise a vector comprising a DNA sequence encoding BMP-2 operably linked to a promoter, and a pharmaceutically acceptable polymer, wherein a biodegradable plate is applied to the site prior to the application of the composition. Claim 2 is dependent on claim 1. As acknowledged by the Office, Moutsatsos et al. does not teach a pharmaceutical composition comprising a plurality of

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bone marrow stromal cells isolated from a subject. Furthermore, Moutsatsos et al. does not teach or suggest a pharmaceutical composition wherein a biodegradable plate is applied to the site prior to the application of the composition. As such, Moutsatsos et al. cannot anticipate the subject matter of the claimed invention, and withdrawal of the rejection is respectfully requested.

The Office rejects claims 1-2 and 4-7 as anticipated under 35 U.S.C. § 102(b) in view of Riew et al. (Calcif. Tissue Int. 63:357-360, 1998). Claim 7 has been cancelled. Claim 1, as amended, is directed to a pharmaceutical composition comprising a plurality of bone marrow stromal cells (MSCs) isolated from the subject. The MSCs comprise a vector comprising a DNA sequence encoding BMP-2 operably linked to a promoter, and a pharmaceutically acceptable polymer. Furthermore, a biodegradable plate is applied to the site prior to the application of the composition. Claims 2 and 4 are dependent on claim 1. Claim 5 is directed to a methods of enhancing new bone, cartilage or connective tissue formation in a subject, wherein BMP-2 protein producing MSCs are generated and a biodegradable plate is applied to a site on the subject before the BMP-2 protein producing MSCs are applied to the site. Claim 6 is dependent on claim 5.

Riew et al. teaches implantation of bone marrow stem cells transduced with a recombinant adenoviral vector expressing human BMP-2 into the L5/L6 interspace of rabbits. Riew et al. does not teach or suggest pharmaceutical compositions applied after the application of a biodegradable plate or methods of enhancing new bone, cartilage or connective tissue formation in a subject requiring application of a biodegradable plate before application of BMP-2 producing MSCs. Thus, Riew et al. does not teach or suggest every limitation of the claimed

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invention and cannot be said to anticipate Applicants' invention. Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-2 and 4-7 are also rejected under 35 U.S.C. § 102(b) in view of Riew et al. (Calcif. Tissue Int. 68:87-94, 2001). As discussed above, the pending claims are directed to pharmaceutical compositions applied after the application of a biodegradable plate or methods of enhancing new bone, cartilage or connective tissue formation in a subject requiring application of a biodegradable plate before application of BMP-2 producing MSCs. Cheng et al. teaches implantation of bone marrow stem cells transduced with a recombinant adenoviral vector expressing human BMP-2 into the L5/L6 interspace of rabbits. Cheng et al. does not teach or suggest pharmaceutical compositions applied after the application of a biodegradable plate or methods of enhancing new bone, cartilage or connective tissue formation in a subject requiring application of a biodegradable plate before application of BMP-2 producing MSCs. Therefore, Applicants' claims are not anticipated by Cheng et al., and reconsideration and withdrawal of this rejection is respectfully requested.

Caplan et al. (U.S. 5,855,619) is directed to merely shows that Pancogene S is a trademark for a sterilized type I collagen solution. As such, Caplan et al. does not cure the deficiencies of Moutsatsos et al., Riew et al. and Cheng et al. and withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

III. Rejections under 35 U.S.C. § 103(a)

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Claims 1 and 3-8 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Moutsatsos et al. (Calcif. Tissue Int. 63: 357-360, 1998), in view of Riew et al. (Calcif. Tissue Int. 63: 357-360, 1998) or Cheng et al. (Calcif. Tissue Int. 68:87-94, 2001). The Office also rejected claims 1, 3, 5 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Riew et al. or Cheng et al. These rejections are respectfully traversed for the reasons set forth below.

Claim 7 has been cancelled. As discussed above, claims 1, 3-6 and 8 are directed to pharmaceutical compositions for application at a site requiring new bone, cartilage or connective tissue formation in a subject, comprising a plurality of bone marrow stromal cells (MSCs) isolated from the subject, wherein the MSCs comprise a vector comprising a DNA sequence encoding BMP-2 operably linked to a promoter, and a pharmaceutically acceptable polymer, wherein a biodegradable plate is applied to the site prior to the application of the composition or methods of enhancing new bone, cartilage or connective tissue formation in a subject requiring application of a biodegradable plate before application of BMP-2 producing MSCs. Neither Moutsatsos et al., Riew et al., nor Cheng et al. teach or suggest pharmaceutical compositions comprising a plurality of bone marrow stromal cells (MSCs) isolated from the subject applied after the application of a biodegradable plate or methods of enhancing new bone, cartilage or connective tissue formation in a subject requiring application of a biodegradable plate before application of BMP-2 producing MSCs. The deficiencies of Moutsatsos et al., Riew et al. and Cheng et al. are not cured by the disclosures of the others or by the disclosure of Caplan et al.. As such, Applicants' claims are not made obvious by the disclosures of Moutsatsos et al., Riew et al. or Cheng et al. and withdrawal of the rejections under 35 § 103(a) is respectfully requested.

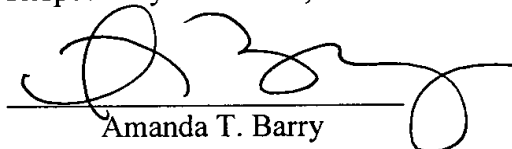
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CONCLUSION

The amendments made herein should in no way be construed as dedicating any unclaimed or amended subject matter or equivalents to the public, and were done solely to expedite prosecution. Applicant reserves the right to pursue any cancelled or amended subject matter in this or related applications.

With entry of the above amendments and in view of the foregoing remarks, it is respectfully submitted that the pending claims are in condition for allowance. The Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully Submitted,



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